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TITLE OF THE INVENTION:

## APPARATUS USABLE IN HAEMOFILTRATION TREATMENT

The present invention relates to an apparatus usable  
10 in CRRT (Continuous Renal Replacement Therapy) treatment.

BACKGROUND OF THE INVENTION

As is known, for various reasons, it may prove  
necessary to supplement or replace the renal function of  
patients to remove waste liquids and soluble substances,  
15 such as substances administered to the patient and/or  
waste substances contained in the blood as a result of  
pathology, surgery, etc.

Various procedures are employed for this purpose,  
including haemodialysis, haemofiltration, and  
20 ultrafiltration, all of which provide for removing waste  
products from the patient. That is, the patient's blood  
is fed through filters or membranes to eliminate the  
waste substances in it, and is then fed back to the  
patient.

25 For patients in grave conditions, procedures include  
Continuous ArterioVenous Haemofiltration (CAVH),  
Continuous VenoVenous Haemofiltration (CVVH), or, in  
general, CRRT as defined above. In this type of

procedure, the patient is connected permanently to the haemofiltration machine for a prolonged period of time.

Examples of known CRRT machines are described in US-5,211,849 and US-6,349,170. That is, a CRRT machine  
5 comprises a central unit connected at the input and output to the patient, e.g. by means of one or more catheters inserted inside corresponding blood vessels, to continuously withdraw the blood for treatment and feed back the treated blood. The central unit of a CRRT  
10 machine normally comprises a blood pump, blood heating and processing means, such as, heparin adding means, means for feeding refill liquid into the blood, and a haemofilter. The blood withdrawn continuously from the patient is thus pumped by the blood pump along the  
15 machine circuit, heparin and appropriately heated refill liquid is added, and the blood is then filtered before being fed back to the patient.

A major drawback of currently used CRRT systems is their slow speed in relation to patient requirements.

20 Another drawback of known CRRT systems is the compulsory use of a pump for the ultrafiltrate, which is less tolerable by chronic, haemodynamically unstable patients whose refill capacity is always unknown.

#### SUMMARY OF THE INVENTION

25 It is a main object of the present invention to eliminate the aforementioned drawbacks.

According to the present invention, there is provided a CRRT apparatus as claimed in Claim 1 and the

dependent Claims.

The advantages of the apparatus according to the present invention substantially lie in greatly improving "decapneisation", i.e. in greatly reducing the CO<sub>2</sub> values of the blood. By way of example, reducing FiO<sub>2</sub> from 100 to 70% has been found to increase O<sub>2</sub> saturation of the patient from 92 to 100%. This is extremely important, in that the poor capacity of the lung to exchange O<sub>2</sub> constitutes a serious complication in many patients. Another advantage lies in the principle of the present invention being applicable to existing machines, which can be altered to achieve more complete, more effective performance. Moreover, the characteristics of an apparatus in accordance with the invention remain unchanged with very little maintenance.

#### BRIEF DESCRIPTION OF THE DRAWINGS

A non-limiting embodiment of the present invention will be described by way of example with reference to the accompanying drawing, in which:

Figure 1 shows, schematically and not to scale, one possible embodiment of a CRRT apparatus in accordance with the present invention.

#### DETAILED DESCRIPTION OF THE INVENTION

Number 1 in Figure 1 indicates as a whole a CRRT apparatus in accordance with the present invention.

Apparatus 1 is connected at the input to a patient P by a first conduit 9, which may be defined, for example, by a Horizon Medical Product DLC600 KC 11.5 Fr or DLC 800

KC femoral catheter. Other means may, of course be used to connect the apparatus to the patient, and data relative to other component parts described herein is also provided purely by way of non-limiting examples.

5 Catheter 9 is connected to a conduit 90, which is fitted with and acted on downstream by a blood pump 3; a gauge 20 is also provided to measure the intake arterial pressure of the patient. The successive portions of the path along which the blood flows are defined by conduit  
10 portions 91, 92, 93, 94 and 95.

Pump 3 pumps the blood downstream (in the direction shown by the arrows) to a connecting member 4, after first adding heparin by means of a conduit 50 connected to conduit 91 and to a heparin tank (syringe) 5. A  
15 conduit 60 is connected to the input of connecting member 4 to supply, by means of a pump 61, a refill liquid or infusion contained in a tank 6 and heated by heating means 62.

A gauge 40 is provided at connecting member 4 to  
20 measure the pressure at that point along the path.

Downstream from connecting member 4, conduit portion 92 is connected to an oxygenating device 7 or "decapneisator", which may be a Jostra Polystan mycro or Jostra Safe mycro neonatal type, and which is connected  
25 by a conduit 77 to an oxygen tank 78, and is fitted inside with an oxygenating membrane 71. Oxygenating device 7 provides for supplying oxygen to eliminate CO<sub>2</sub> from the blood; for which purpose, CO<sub>2</sub> is eliminated

through an outlet 70 of device 7 and sent to measuring means not shown.

Downstream from "decapneisator" 7, conduit portion 93 is connected to a blood filter or haemofilter 8 having an output connected to a conduit 80 for discharging ultrafiltrate into a collecting tank 81. Conduit 80 is fitted with control means 82, which may be defined, for example, by a detector for detecting blood loss in the ultrafiltrate, and which acts directly on conduit 80.

10 Blood filter 8 may be a currently marketed type, such as a MEDICA company MEDISULFONE D200 haemofilter.

Apparatus 1 according to the present invention advantageously does not employ an ultrafiltrate pump, in that, using oxygenating device 7, ultrafiltration takes place naturally, in a more physiologically correct manner.

Downstream from filter 8, conduit portion 94 is connected to a member 49 defined by a venous vessel and having a gauge 48 for measuring the pressure of the return blood to the patient.

Downstream from member 49, conduit portion 95 - which is fitted with an air detector 47 to prevent emboli (e.g. a UABD ultrasonic air bubble detector) - is connected to a return catheter 9' for feeding the blood back to patient P.

In other words, an apparatus in accordance with the present invention comprises a CRRT machine, and an oxygenating device or "decapneisator". By way of example,

the CRRT machine may be an Equasmart Medica equipped with appropriate connecting tubes, catheters, connections, etc.

Testing has revealed numerous advantages.

5 In particular, the apparatus is advantageous in all cases in which the oxygen concentration of the blood requires supplementing, and especially in eliminating CO<sub>2</sub> in patients in which correct substitute respiration therapy is difficult to apply.

10 In actual use, the apparatus is connected to the patient undergoing CVVH treatment, and a patient weight loss is set as required. For example, a total weight loss of 2400 g and an hourly loss of 100 g may be programmed. These two parameters determine a treatment time of 24  
15 hours. Administration of an anticoagulant equal to 1.5 times the blood coagulation time may be set; in which case, a pump flow rate (QB) of 280-300 ml/min and an oxygen flow rate (QO<sub>2</sub>) of 500 ml/min will be programmed.

At therapy method level, with the present invention,  
20 the patient is connected to a CRRT machine, using an oxygenating device located and acting upstream from the blood filter and downstream from the blood pump. This location of the oxygenating device is particularly important. In fact, it means the oxygenating membranes of  
25 the oxygenating device operate without the intake (negative) pressure along the portion upstream from the blood pump, and also without the blood concentration characteristic of the venous portion, which could

eventually impair their efficiency.

Again at therapy level, a weight loss (i.e. the quantity of liquid to be drained) may be set as required in each specific case, i.e. as prescribed by the physician. An anticoagulant infusion in line with standard CRRT protocols will therefore be provided, with a blood flow rate (QB) of over 300 ml/min, and an oxygen flow rate (QO<sub>2</sub>) higher than QB. It is important to continuously monitor both coagulation time, which must be kept constantly at one and a half times normal, and oxygen saturation, haematocrit, blood volume values, etc. For this purpose, a CRITE-LINE or similar apparatus may be used.

Clearly, changes may be made to the form, dimensions, component part locations, and type of materials employed in the embodiment described and illustrated herein without, however, departing from the scope of the present invention.